UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

March 27, 2013

MEMORANDUM

SUBJECT: Acute Toxicity Review for EPA Reg. No.: 9428-T
DP Barcode: D406465

FROM: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Chris Jiang
3/27/13

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Monisha Harris PM 32/David Liem
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Sun-Pine Corporation

FORMULATION FROM LABEL:

Active Ingredient(s):	
Sodium hypochlorite	8.25 %
Inert Ingredient(s):	91.75 %
Total:	100.00 %

(Yields 7.86% available chlorine)
Contains no phosphorus

BACKGROUND: The registrant has submitted an acute toxicity package to register this end-use product to be used as a disinfectant. The package includes a label, a Confidential Statement of Formula, a data matrix, an acute inhalation study (MRID 48974105), and a dermal sensitization study (MRID 48974106). The instructions state that the product is similar to EPA Registration Number 5813-100.

FINDINGS:

1. The registrant may not cite 5813-100 because this product and 5813-100 are different in inert ingredients.

2. The acute toxicity profile for 9428-T is:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	00007397 00007399	?	Acceptable
Acute Dermal Toxicity	00007398	?	Acceptable
Acute Inhalation Toxicity	48974105	IV	Acceptable
Primary Eye Irritation	00008204 00008206	?	Acceptable
Primary Skin Irritation	00008203 00008205	?	Acceptable
Dermal Sensitization	48974106	Sensitizer	Acceptable

LABELING

1. No labeling or first aid statements can be prescribed at the present time.

DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

Product Manager: Monisha Harris
MRID No.: 48974105

Reviewer: Chris Jiang
Study Completion Date: June 6, 2012
Report No.: 33881

Testing Laboratory: Product Safety Labs
Author: Aija McKenzie

Quality Assurance (40 CFR 160.12): A statement of GLP compliance was included.

Test Material: SP Ultra 8 Disinfectant Cleaner, lot#: 110311/1, clear yellow liquid

Dosage: 2.10 mg/L
(Nominal concentration: 25.97 mg/L) (Gravimetric concentration: 2.10 mg/L)

Species: Five male and five female derived albino Sprague-Dawley rats
Age: Nine to ten weeks at study start
Weight: ♀: 174 to 195 grams at study start; ♂: 240 to 255 grams at study start
Source: Harlan Laboratories

Summary:

1. **LC_{50} (mg/L)** : > 2.10 mg/L
2. **The LC_{50} is greater than 2.10 mg/L.**
3. **MMAD**: 2.70 µm
4. **Toxicity Category**: IV **Classification**: Acceptable

Procedure (Deviations from 81-3): No deviations occurred during the study.

Results:

Reported Mortality

Dosage (mg/L)	(Number Deaths/Number Tested)		
	Males	Females	Combined
2.10	0/5	0/5	0/10

Chamber Atmosphere			
Dose Level (mg/L)	MMAD (µm)	GSD (µm)	% particles < 3.3 µm
2.10	2.77	2.05	49.2
2.10	2.62	1.96	49.9

Chamber Environment During Exposure

Chamber Volume (L)	28
Average Total Airflow Volume (Lpm)	36.0
Air Changes Per Hour	77
Mean Temperature (°C)	19 to 20
Mean Relative Humidity (%)	26 to 29

Clinical Observations: Due to abnormal respiration, the study was extended to verify the reversal of this sign. Additional signs included weight loss, reduced fecal volume, alopecia, and rales.

Gross Necropsy Findings:

Gross necropsies were unremarkable.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (81-6, 870.2600)

Product Manager: Monisha Harris
MRID No.: 48974106

Reviewer: Chris Jiang
Study Completion Date: June 5, 2012
Study Amended Date: June 6, 2012
Report No.: 33882

Testing Laboratory: Product Safety Labs
Author: Aija McKenzie

Quality Assurance (40 CFR 160.12): A statement of GLP compliance was included.

Test Material: SP Ultra 8 Disinfectant Cleaner, lot#: 110311/1, clear yellow liquid
Positive Control: α-Hexylcinnamaldehyde (HCA)

Species: Male Hartley albino guinea pig
Weight: 350 to 461 grams at study start
Age: Young adult
Source: Elm Hill Breeding Labs, Chelmsford, MA

Method: Buehler Method

Summary:

1. **This Product is a dermal sensitizer.**
2. **Classification**: Acceptable

Procedure (Deviation From §81-6): No deviations occurred during the study.

Procedure: After preliminary tests, the definitive study was undertaken. Once each week for three weeks, either 0.4 mL of a 50% solution of the test material or nothing was applied to the clipped left side of each animal using gauze patches. After chamber application, the trunks of the animals were wrapped with elastic wrap that was secured with adhesive tape. After the exposure period, the chambers and bindings were removed and the test sites were cleansed of residual test substance. The guinea pigs were scored at 24 and at 48 hours after each induction. Twenty-eight days after the first induction, all animals were challenged with 0.4 mL of a 25% test substance in distilled water on the right side. The guinea pigs were scored at 24 and at 48 hours after challenge.

Results: At 24 hours after each induction, all animals had faint erythema with or without dark discoloration. At 48 hours after the first induction, eleven animals had faint erythema with or without dark discoloration and nine animals experienced very faint erythema with or without dark discoloration. At 24 hours after the second induction, eleven animals had moderate erythema with or without dark discoloration and nine animals had faint erythema with or without dark discoloration. At 48 hours after the second induction, At 48 hours after the second induction, twelve guinea pigs had moderate erythema with or without dark discoloration and eight animals had faint erythema with or without dark discoloration. At 24 hours after the third

induction, two animals had severe erythema with or without edema, eleven animals had moderate erythema with or without dark discoloration, and seven test subjects had faint erythema. At 48 hours after the third induction, two animals had severe erythema, with dark discoloration, fourteen animals had moderate erythema with or without dark discoloration, and four guinea pigs had faint erythema with or without dark discoloration.

The historical positive control showed appropriate results.